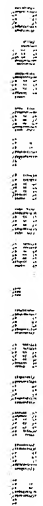


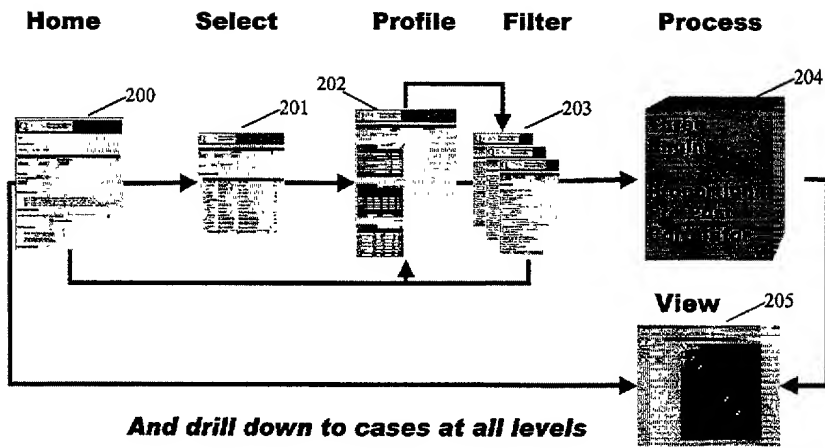
## Figures

FOUO - GET 2000

Table 1. Demographic characteristics of the study population	
Age (years)	65.0 ± 1.5
Gender	
Male	50.0
Female	50.0
Education (years)	12.0 ± 1.0
Income (USD/month)	1,200.0 ± 200.0
Marital status	
Married	60.0
Single	40.0
Health status	
Good	70.0
Poor	30.0
Smoking status	
Smoker	30.0
Non-smoker	70.0
Alcohol consumption	
Drinker	20.0
Non-drinker	80.0
Comorbidities	
Hypertension	40.0
Diabetes	20.0
Cholesterol	30.0
Arthritis	10.0
Depression	15.0
Medication use	
Yes	60.0
No	40.0
Quality of life (SF-36)	50.0 ± 10.0
Physical function	40.0 ± 8.0
Role limitation	30.0 ± 7.0
Bodily pain	45.0 ± 9.0
General health	55.0 ± 11.0
Vitality	40.0 ± 8.0
Social functioning	45.0 ± 9.0
Emotional well-being	50.0 ± 10.0
Health transitions	
Stable	60.0
Unstable	40.0
Healthcare utilization	
Regular	70.0
Irregular	30.0
Healthcare costs (USD/year)	1,500.0 ± 300.0
Health insurance status	
Insured	80.0
Uninsured	20.0
Healthcare access	
Good	70.0
Poor	30.0
Healthcare satisfaction	
Satisfied	60.0
Dissatisfied	40.0
Healthcare quality	
High	70.0
Low	30.0
Healthcare equity	
High	70.0
Low	30.0
Healthcare transparency	
High	70.0
Low	30.0
Healthcare accountability	
High	70.0
Low	30.0
Healthcare effectiveness	
High	70.0
Low	30.0
Healthcare efficiency	
High	70.0
Low	30.0
Healthcare safety	
High	70.0
Low	30.0
Healthcare patient-centeredness	
High	70.0
Low	30.0
Healthcare equity	
High	70.0
Low	30.0
Healthcare transparency	
High	70.0
Low	30.0
Healthcare accountability	
High	70.0
Low	30.0
Healthcare effectiveness	
High	70.0
Low	30.0
Healthcare efficiency	
High	70.0
Low	30.0
Healthcare safety	
High	70.0
Low	30.0
Healthcare patient-centeredness	
High	70.0
Low	30.0

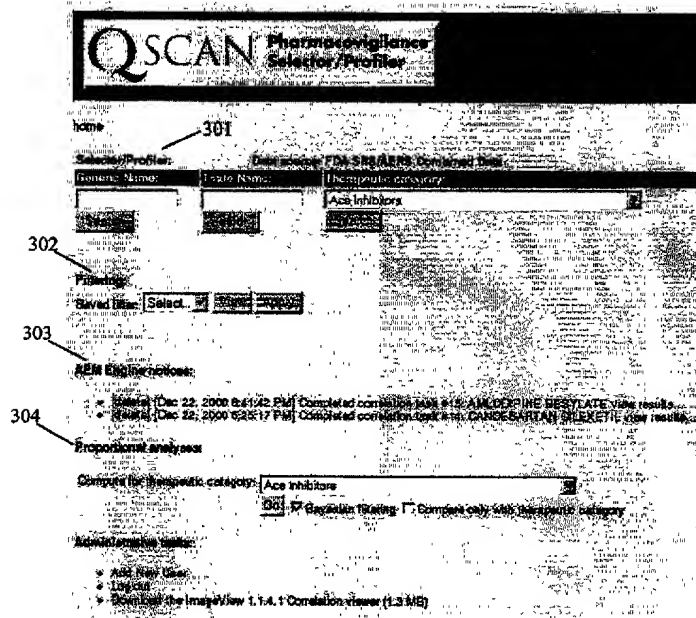


**Figure 2**



FOUO 323232

Figure 3



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### Figure 4

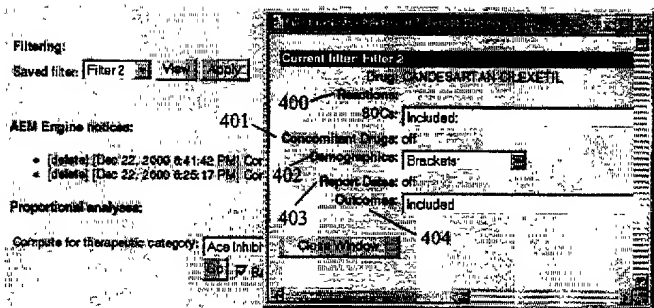


Figure 5

home > drug selector

500

Selector/Profiler: 501

Date source: FDA SRS/AERS Combined Data

Generic Name: Trade Name: Therapeutic category:

502

Filtering:

Saved filter: Select View

22 drugs in category: ACE INHIBITORS

Generic Name	Trade Names	Therapeutic Categories	Pedigree
AMLODIPINE HYDROCHLORIDE	AMLODIPINE	Ace Inhibitors	?
AMLODIPINE BESYLATE	AMLODIPINE	Ace Inhibitors	?
BENAZEPRIL HYDROCHLORIDE	BENAZEPRIL	Ace Inhibitors	?
CANDESARTAN CILEXETIL	ATACAND	Ace Inhibitors	?
CAPTORIL	ACE-HEMMER	Ace Inhibitors	?
ENALAPRIL MALEATE	ACE-TENSIL	Ace Inhibitors	?

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# Figure 6

600	Data Pedigree	601	602	603	604	605	606	607
Map To	Verbatim	Source	Incidents	Case Count	QEDRx Processing	Cross-reference	First/Last Reported Reactions	
PROZAC	PROZAC	SRS	47953	47937		Orange Book	Apr 27 1989/Dec 2 1997	
PROZAC	Prozac	AERS	3378	3308 S		Orange Book	Nov 1 1987/Jun 29 1999	
FLUOXETINE	FLUOXETINE HYDROCHLORIDE	SRS	2204	2203		NDCCD Tradename	Jan 1 1979/Oct 14 1997	
FLUOXETINE	Fluoxetine	AERS	574	571 S		NDCCD Tradename	Nov 1 1987/Jun 18 1998	
PROZAC	Prozac (Fluoxetine Hydrochloride)	AERS	379	378	M	Orange Book	Nov 1 1997/Jun 12 1999	
PROZAC	Prozac (Fluoxetine)	AERS	140	140	M	Orange Book	Nov 7 1997/Apr 24 1999	
FLUOXETINE	Fluoxetine Hydrochloride	AERS	122	122 S		Orange Book	Nov 14 1997/Jun 27 1999	
FLUOXETINE	Fluoxetine (Fluoxetine Hydrochloride)	AERS	65	65	M	Orange Book	Mar 1 1998/Jun 24 1999	
FLUOXETINE	Fluoxetine Hcl	AERS	34	34		Orange Book	Nov 1 1997/Nov 1 1998	
PROZAC	Prozac (Fluoxetine Hcl)	AERS	20	20	M	Orange Book	Nov 1 1997/Mar 12 1999	
PROZAC	Prozac (Fluoxetine Hydrochloride)	AERS	17	17	M	Orange Book		
FLUOXETINE	Fluoxetine (Fluoxetine)	AERS	15	15	M	Orange Book	Nov 15 1997/Jun 6 1999	

PROZAC 3378

# Figure 7

700

701

Reactions

View: HLT (258 of 1495) filter

702

Top 10 HLTs of 258	Reaction Count	% of Reactions
Hypertension and increased blood pressure NEC	68	3.88%
General symptoms and signs NEC	57	3.25%
Disturbances in consciousness	52	2.97%
Renal function analyses	46	2.63%
Headaches NEC	46	2.63%
Cardiac function diagnostic procedures	48	2.63%
Neurological signs and symptoms NEC	45	2.57%
Nausea and vomiting (all forms)	43	2.45%
Asthenic conditions	43	2.45%
Vascular tests NEC including blood pressure	42	2.40%
Top 10 HLTs	488	Total reactions 1752

704

703

more details

TABLE 33-33



Figure 8

Concomitant Drugs

801 802 filter.

Top 10 drugs	Suspect		Non-suspect		Total	%
	S	NS	S	NS		
HYDROCHLOROTHIAZIDE	9	36	0	0	45	10.79%
ASPIRIN	2	38	0	5	45	10.79%
FUROSEMIDE	2	32	0	1	35	8.39%
DIGOXIN	0	30	0	0	30	7.18%
AMLODIPINE BESYLATE	0	24	4	0	28	6.71%
ENALAPRIL MALEATE	4	15	0	5	24	5.76%
VERAPAMIL HYDROCHLORIDE	11	10	0	2	23	5.52%
ESTROGENS, CONJUGATED	0	23	0	0	23	5.52%
METOPROLOL SUCCINATE	8	11	0	3	22	5.28%
METOPROLOL TARTRATE	0	15	0	7	22	5.28%
Non-Suspect suspect						
Total		Total		Total		
172		1141		1313		

more details...

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# Figure 9

900

Demographics

901

filter

Age Group	Male	Female	Unknown	Total	%
>75	18	73	0	91	21.82%
51-75	89	123	1	213	51.08%
31-50	30	16	0	46	11.03%
16-30	2	1	0	3	0.72%
<16	0	0	0	0	0.00%
Unknown	11	30	23	64	15.35%
Total	150	243	24	417	
%	35.97%	58.27%	5.76%		

more details

FOIA b 7 - D

Figure 10

Report Dates 1000 1001 filter 1002

Timeframe	Count	%
1990-1999	446	100.00%
Total Report Dates		
	446	

more details..

FOIA b 7 - Exemption

**Figure 11**

Outcomes Filter...

Outcome	Count	%
DEATH	36	7.19%
DISABILITY	18	3.59%
HOSPITALIZATION - INITIAL OR PROLONGED	231	46.11%
LIFE-THREATENING	45	9.18%
OTHER	168	33.53%
REQUIRED INTERVENTION TO PREVENT PERMANENT IMPAIRMENT/DAMAGE	2	0.40%
Total serious outcomes	333	
Total non-serious outcomes	168	
Total outcomes	501	

[more details...](#)

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Figure 12

Reactions | Drugs | Outcomes | Report Sources | Timeframes | Demographics | Cases | Filter Notes

deafness

Reactions

- ☒ blood and lymphatic system disorders
- ☒ cardiac disorders
- ☒ congenital and familial/genetic disorders
- ☒ ear and labyrinth disorders
- ☒ external ear disorders (exc congenital)
- ☒ hearing disorders
- ☒ deafness and hyperacusis
  - ☒ deafness conductive (exc otosclerosis)
  - ☒ deafness neurosensory
  - ☒ deafness permanent
  - ☒ deafness transient
  - ☒ dysacusis
  - ☒ hearing impaired
  - ☒ hearing impairment acoustical
  - ☒ hyperacusis
  - ☒ hypoacusis
  - ☒ presbycusis
- ☒ inner ear and with cranial nerve disorders
- ☒ middle ear disorders (exc congenital)
- ☒ miscellaneous ear disorders
- ☒ endocrine disorders
- ☒ eye disorders
- ☒ gastrointestinal disorders

Generate profile for this filter (This Filter has not been profiled)

FOI 2009-0331260

# Figure 13

Below are the top 200 correlated terms for your analysis on CANDESARTAN CILEXETIL (Rank 95). View with Image View

Correlated Terms					
[Rank]	[Score]	[Term 1]	[Category]	[Term 2]	[Category]
1	7706	Female	Sex	CANDESARTAN CILEXETIL	Target Drug
2	7661	Renal function analyses	Other Reaction	Renal failure and impairment	Other Reaction
3	7244	Paralysis (exc. congenital and cranial nerve)	Other Reaction	Central nervous system haemorrhages and cerebrovascular accidents	Other Reaction
4	6901	HOS	Outcome	CANDESARTAN CILEXETIL	Target Drug
5	6888	TRIAMTERENE	Other Drug	DICLOFENAC SODIUM	Other Drug
6	6286	OTH	Outcome	CANDESARTAN CILEXETIL	Target Drug
7	5868	Sex Not Specified	Sex	Age Not Specified	Age
8	5773	VERAPAMIL	Other Drug	TRIAMTERENE	Other Drug
9	5765	HOS	Outcome	Female	Sex
10	5753	Male	Sex	CANDESARTAN CILEXETIL	Target Drug

1303 1304 1300 1305 1302 1306

# Figure 14

Correlation Details:  
Analyzed Drug: CANDESARTAN CILEXETIL  
Cases for term pair: Renal function analyses [Other Reaction] / Renal failure and impairment [Other Reaction]

1401 Cases 1 to 18 of 18 cases 1402 1403 1404 1405 1406 1407 1408

Case ID	Sex	Manufacturer Control Code	FDA Report Receipt Date	Age	Drugs	Reactions	Serious
1 3263641	F	19990300088	1999-06-17	74	Atacand	Blood Creatinine Increased; Dialysis Nos; Renal Failure Aggravated	N
2 3198047	F	19990200143	1999-03-12	57	Acuretic, Atorvastatin, Atacand, Cefixime, Nitro-Dur, Terbasmin Expectorants	Blood Creatinine Increased; Blood Urea Increased; Hypotension NOS; Renal Failure Acute	Y
3 3171644	F	19981100002	1999-01-17	69	Xanax, Acetylsalicylic Acid, Wellbutrin, Atacand, Arthrotec, Digoxin, Levaquin, Clonidine, Antivert, Pyndium, Zolof, Dyazide, Verapamil - Slow Release, Ambien	Abdominal Pain Nos; Blood Creatinine Increased; Blood Urea Increased; Coronary Artery Disease Nos; Haemoptysis; Heart Rate Increased; Hypertension Aggravated; Renal Failure Acute	N
4 3270258	F	19990400499	1999-06-26	75	Atacand, Hydrochlorothiazide	Arrhythmia; Atrial Fibrillation; Atrioventricular Block Second Degree; Blood Creatinine Increased; Blood Pressure Decreased; Electrocardiogram ST Segment Depression; Electrocardiogram T Wave Abnormalities; Electrolyte Imbalance; Hyponatremia; Hypokalaemia; Hypotension; Loss Of Consciousness Nac; Renal Impairment Nos; Syncope	N

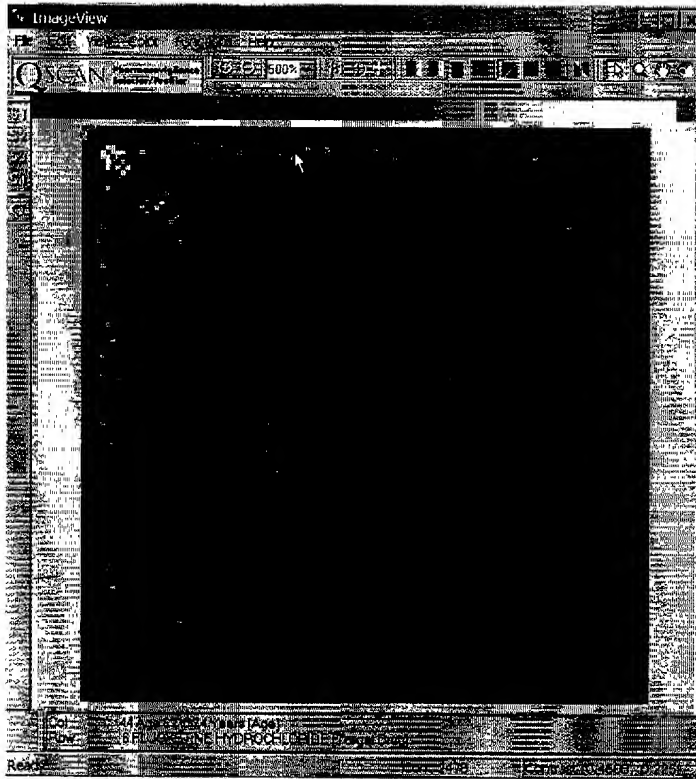
FOI 050 63472360

Figure 15

<b>Correlation Details</b>						
Analyzed Drug: CANDESARTAN CILEXETIL						
Case for term pair: Renal function analyses [Other Reaction] / Renal failure and impairment [Other Reaction]						
1501	Case ID:	3198047				
1502	Sex:	F				
1503	Age:	57.0 years, 0.0 months				
1504	Reactions	As Reported	Preferred Term	High Level Term	High Level Group Term	System Organ Class
		Blood Creatinine Increased	Blood Creatinine Increased	Renal function analyses	Renal and urinary tract investigations and unnlaysis	Investigations
		Blood Urea Increased	Blood Urea Increased	Renal function analyses	Renal and urinary tract investigations and unnlaysis	Investigations
		Hypotension NOS	Hypotension NOS	Hypotension	Decreased and non-specific blood pressure disorders and shock	Vascular disorders
		Renal Failure Acute	Renal Failure Acute	Renal failure and impairment	Renal disorders (exc nephropathies)	Renal and urinary disorders
1505	Concomitant Drugs:	Name	Dose	Route	Suspect Status	
		Abiraterone	TAB QD		Yes	
		Atorvastatin			No	
		Alacand	16 MG QD PO ORAL		Yes	
		Ceftriaxone			No	
		Nitro-Dur			No	
		Terbutaline Expectorante			No	
1506	Outcomes:	HOSPITALIZATION - INITIAL OR PROLONGED (HQ) LIFE-THREATENING(LT)				
1507	Manufacturer Control Code:	19990200143				
1508	Manufacturer Date:	1999-03-5				
1509	Adverse Event Date:	1998-12-13				
1510	Report Type:	EXP				
1511	Report Source:	OTH				
1512	Case Source:	AERS				
1513	Narrative:					



Figure 16



FOR OFFICIAL USE ONLY

Figure 17

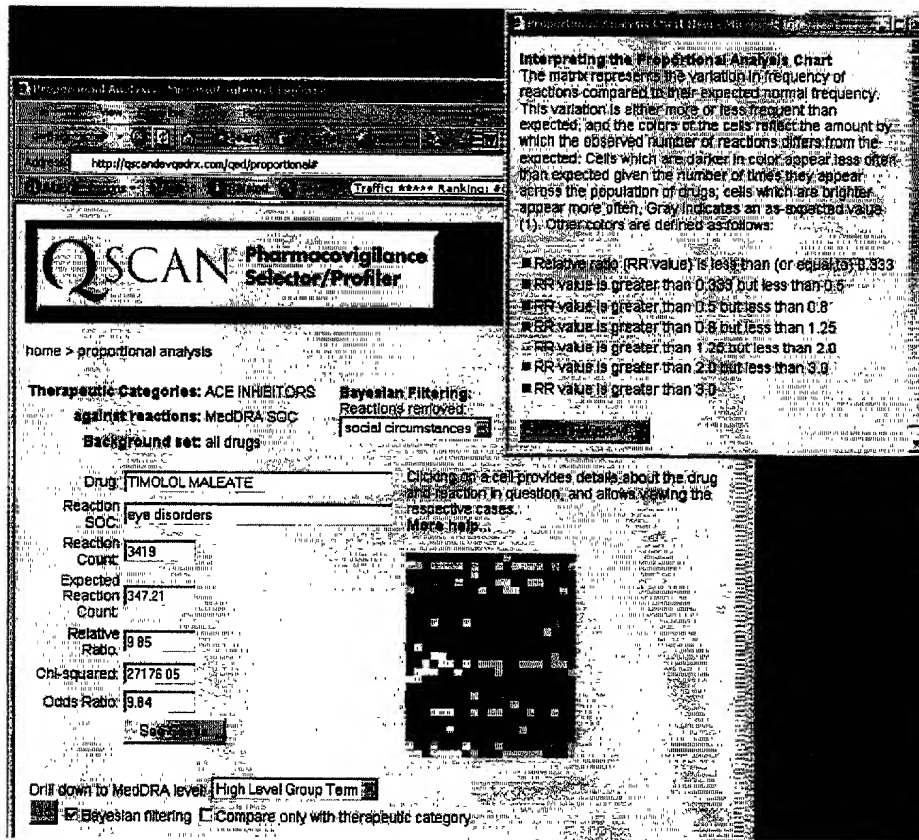


Figure 18

Proportional Analysis  
[ACE INHIBITORS] vs. Reactions (SOCs)  
View by HLGTs

1800	Drug	AMLODIPINE BESYLATE
1801	Reaction	Surgical and medical procedures
1802	Reaction Count	927
1803	Expected Reaction Count	201.02
1804	Relative Ratio	4.61

T02050"685T0350

# Figure 19

550 entries for this analysis are displayed below.

Correlated Terms		1900	1901	1902	1903	1904
[Reaction]	[Drug]	[Count]	[Expected Count]	[Relative Ratio]		
1 6 Eye disorders	19. TIMOLOL MALEATE	3392	346.3	9.8		
2 24: Surgical and medical procedures	2. AMLODIPINE BESYLATE	1732	200.4	8.6		
3 14: Metabolism and nutrition disorders	1. AMILORIDE HYDROCHLORIDE	639	266.5	3.1		
4 24: Surgical and medical procedures	13. METHYLDOPA	37	15.6	2.4		
5 16: Neoplasms benign and malignant (including cysts and polyps)	17. RESERPINE	65	28.6	2.3		
6 24: Ear and labyrinth disorders	4. CANDESARTAN CILEXETIL	32	14.3	2.2		
7 24: Surgical and medical procedures	20. TRANDOLAPRIL	13	6	2.2		
8 14: Metabolism and nutrition disorders	18. SPIRONOLACTONE	1350	618.1	2.2		

FOR 2020 035 FEB 20

Figure 20

OSCAR

2002 2003 2004 2005 2006 2007 2008

Year	Category	Value	Value	Value	Value	Value	Value
2001	Admission	4.00%	2.00%	2.00%	2.00%	2.00%	2.00%
2000	Resident	4.00%	2.00%	2.00%	2.00%	2.00%	2.00%
2000	Transfer	4.00%	2.00%	2.00%	2.00%	2.00%	2.00%
2010	Transfer	4.00%	2.00%	2.00%	2.00%	2.00%	2.00%
2009	Transfer	4.00%	2.00%	2.00%	2.00%	2.00%	2.00%
2013	Transfer	4.00%	2.00%	2.00%	2.00%	2.00%	2.00%
2012	Transfer	4.00%	2.00%	2.00%	2.00%	2.00%	2.00%

2001 2000 2010 2009 2013 2012

Figure 21

home > drug selection > drug profile > case list

Drug: BENAZEPRIL HYDROCHLORIDE  
 Reaction: SOCs: Included  
 Concomitant Drug(s):  
 Demographics of:  
 Report Dates of:  
 Outcomes of:

Summary View... Cases: 1 to 60 of 286 cases  
 6 pages: 1 51 101 151 201 251 2101 2102 2103 2104 2105 2106 2107

Case ID	Sex	Manufacturer Control Code	IRB Report Receipt Date	Age	Drugs	Reactions	Sections
1 3510123	F	200010174B8E	2000-06-1		Tylenol, Albuterol, Dantrolene C Pm, Aspirin, Acetaminophen Ex Bid, Amlodipine, Lotensin, Zyrtec, Doxycycline, Benadryl, Premarin, Lexapro, Hctz 25 Mg, Hydrocodone, Immune Globulin Intravenous (Human), Gantrisin N 10% - Placido, Iodine, Xylocaine, Clonidine, Glucophage, Methylphenidate Hcl, Nicorette, Singulair, Phoslo, Oxygen, Paxil, Salumetrol Pack, Razulin 200 Mg Am	Cardiac Monitor Nos: Dyspnea, Dyspnea Nos, Oedema Lower Limb; Pain In Limb, Phlebitis Nos, Physical Examination Nos Abnormal, Rhenorrhea, Tenderness Nos, Venous Thrombosis Deep Limb	Y
2 031979033	F	97USA40861	1997-08-13		LOTENSIN	Hypertension NOS, Tachycardia NOS	N
3 3204965	F	99061672	1999-08-26		Aspirin Coated, Lotensin, Niaspan	Asthma, Dizziness (Exc Vertigo), Dyspnea, Flushing, Pain Nos	Y
4 001466473	F	830644001	1994-05-29		LOTENSIN	Rhinitis, Vasodilation	N

TO 2000-03-23 09:00